

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

JANSSEN PHARMACEUTICA N.V.,)	
JANSSEN, L.P., and SYNAPTECH, INC.,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 05-420-KAJ
)	
ALPHAPHARM PTY., LTD.)	
)	
Defendant.)	
)	

**ANSWER TO COMPLAINT FOR PATENT
INFRINGEMENT AND COUNTERCLAIMS**

Defendant, Alphapharm Pty., Ltd. (“Alphapharm”) answers the Complaint of Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc., (collectively “Plaintiffs”) as follows:

1. Alphapharm states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 1 of the Complaint, and on that basis denies the allegations set forth therein.
2. Alphapharm states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 2 of the Complaint, and on that basis denies the allegations set forth therein.
3. Alphapharm states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 3 of the Complaint, and on that basis denies the allegations set forth therein.

4. Alphapharm admits that it is a corporation organized under the laws of Australia with a principal place of business at Chase Building 2, 1 Wentworth Park Road, Glebe NSW 2037 Australia. Alphapharm admits that it conducts business in the United States, in Delaware, and in this district.

Jurisdiction and Venue

5. This averment constitutes a conclusion of law to which no response is deemed necessary. To the extent one is deemed necessary, Alphapharm admits that this court has original jurisdiction of the subject matter for each of the claims in this Complaint and that patent infringement is a claim arising under the patent laws of the United States, Title 35, U.S.C. § 271 *et seq.*, and 21 U.S.C. § 355, with original jurisdiction in this Court by virtue of 28 U.S.C. §§ 1331 and 1338(a). Alphapharm denies that Plaintiffs' claims are valid or have merit.

6. Alphapharm admits that this Court has jurisdiction over Alphapharm for the purposes of this action.

7. This averment constitutes a conclusion of law to which no response is deemed necessary.

Regulatory Requirements for Approval of New and Generic Drugs

8. Admitted.

9. Admitted.

10. Admitted.

11. Admitted.

12. Admitted.

Plaintiffs' Approved Drug Product

13. Alphapharm states that it is without knowledge or information sufficient to form a belief as to the truth of averments of Paragraph 13, and on that basis, denies them.

14. Alphapharm admits that the commercial formulation of galantamine hydrobromide tablets approved by the FDA for the treatment of mild to moderate dementia of the Alzheimer's type is sold under the trademark RAZADYNE®. Alphapharm admits that Janssen formerly marketed its galantamine hydrobromide tablets under the trademark REMINYL®.

15. Denied. The FDA, pursuant to Janssen's request, has listed the '318 patent in the Orange Book.

16. Alphapharm admits it has not previously challenged the listing of the '318 patent in the Orange Book. Alphapharm denies that the '318 patent has any valid claims for an approved use of the drug product that is the subject of NDA No. 21-169 such that it qualifies for listing in the Orange Book. Alphapharm further denies the remaining allegations set forth in Paragraph 16 of the Complaint.

Alphapharm's ANDA

17. Admitted.

18. Admitted.

19. Admitted.

Count 1: Patent Infringement

20. Alphapharm realleges its responses to the allegations contained in Paragraphs 1-19 above as if fully set forth herein.

21. Alphapharm denies that United States Patent No. 4,663,318 ("the '318 patent") was duly and legally issued. Alphapharm admits that the '318 patent is entitled "Method of Treating Alzheimer's Disease" and states on its face that it was issued May 5, 1987. Alphapharm states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 21 of the Complaint and on that basis denies the remaining allegations.

22. Alphapharm states that it is without knowledge or information sufficient to form a belief as to the truth of the allegation set forth in Paragraph 22 of the Complaint, and on that basis denies the allegation set forth therein.

23. Alphapharm states that it is without knowledge or information sufficient to form a belief as to the truth of the allegation set forth in Paragraph 23 of the Complaint, and on that basis denies the allegation set forth therein.

24. Alphapharm states that it is without knowledge or information sufficient to form a belief as to the truth of the allegation set forth in Paragraph 24 of the Complaint, and on that basis denies the allegation set forth therein.

25. Alphapharm denies the allegations set forth in Paragraph 25 of the Complaint.

26. Alphapharm denies the allegations set forth in Paragraph 26 of the Complaint.

27. Alphapharm denies the allegations set forth in Paragraph 27 of the Complaint.

28. Alphapharm denies the allegations set forth in Paragraph 28 of the Complaint.

29. Alphapharm admits that it had knowledge of the '318 patent prior to filing ANDA No. 77-603. Alphapharm denies that this knowledge can or does form the basis for a finding of willful infringement and as such denies the remaining allegations set forth in Paragraph 29 of the Complaint.

30. Alphapharm denies the allegations set forth in Paragraph 30 of the Complaint.

First Affirmative Defense

31. The manufacture, use, offering for sale, sale or importation of the galantamine hydrobromide tablets that are the subject of ANDA No. 77-603 will not infringe directly or indirectly any valid claim of the '318 patent.

32. Alphapharm's filing of its ANDA No. 77-603 did not infringe any valid claim of the '318 patent.

Second Affirmative Defense

33. Each claim of the '318 patent is invalid for failure to satisfy one or more of sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code.

Third Affirmative Defense

34. At least one of the Plaintiffs lacks standing to assert infringement of the '318 patent by Alphapharm.

PRAYER FOR RELIEF

WHEREFORE, defendant Alphapharm Pty Ltd. respectfully requests that:

- a) The Complaint of Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. be dismissed with prejudice;
- b) The filing of Alphapharm's ANDA No. 77-603 be found not to infringe any valid claim of the '318 patent;
- c) The manufacture, use, offering for sale, sale or importation into the United States of Alphapharm's galantamine hydrobromide tablets that are the subject of Alphapharm's ANDA No. 77-603 be found not to infringe any valid claim of the '318 patent;
- d) The '318 patent be found invalid;
- e) Alphapharm be awarded its costs in this action;
- f) Alphapharm be awarded its attorneys' fees pursuant to 35 U.S.C. § 285; and
- g) Alphapharm be awarded such other and further relief as this Court may deem just and proper.

COUNTERCLAIMS

Jurisdiction and Venue

1. These counterclaims seek declaratory judgments pursuant to 28 U.S.C. §§ 2201 and 2202.
2. This Court has jurisdiction over these counterclaims pursuant to Title 35 U.S.C. and 28 U.S.C. §§ 1331 and 1338(a).
3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.
4. A justiciable controversy exists between the parties hereto with respect to validity, scope, and infringement of certain claims of U.S. Patent No. 4,663,318 (“the ‘318 patent”).

Acts Giving Rise to this Action

5. On information and belief Janssen Pharmaceutica N.V. is the holder of approved NDA No. 21-169 for galantamine hydrobromide tablets in dosages of 4, 8, and 12 mg.
6. On information and belief Janssen Pharmaceutica N.V. caused the ‘318 patent to be listed in the FDA publication entitled “Approved Drug Products With Therapeutic Equivalence Evaluations” (the “Orange Book”) as a patent which claims the drug for which Janssen Pharmaceutica N.V. submitted NDA No. 21-169 or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, or in the method of using the drug. On information and belief, Synaptech, Inc. is the record owner of the ‘318 patent and Janssen Pharmaceutica N.V. is the exclusive licensee.

7. Alphapharm submitted its ANDA No. 77-603 to obtain FDA approval to engage in the commercial manufacture, use and sale of galantamine hydrobromide tablets, prior to the expiration of the '318 patent.

8. Alphapharm sent letters dated May 11, 2005 ("Notification Letters") to Janssen Pharmaceutica Products, L.P., Janssen Pharmaceutica N.V. and Synaptech, Inc., notifying each that Alphapharm's ANDA No. 77-603 was received by the FDA, and that Alphapharm's ANDA contained a "paragraph IV certification" that the '318 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the product described in Alphapharm's ANDA.

9. On June 21, 2005, Plaintiffs filed the instant suit asserting infringement of the '318 patent.

10. Plaintiffs' filing of the Complaint has created a reasonable apprehension on the part of Alphapharm that Janssen Pharmaceutica Products, L.P., Janssen Pharmaceutica N.V. and/or Synaptech, Inc. will assert that Alphapharm's making, using, selling, offering to sell, or importing of the product described in Alphapharm's ANDA No. 77-603 infringes or will infringe the '318 patent.

First Counterclaim

11. Alphapharm realleges the allegations contained in the preceding paragraphs 1-10 as if fully set forth herein.

12. The manufacture, use, offer to sell, sale, and/or importation into the United States of the galantamine hydrobromide tablets that are the subject of Alphapharm's ANDA No. 77-603 will not infringe directly or indirectly any valid claim of the '318 patent. Nor did the filing of Alphapharm's ANDA infringe any valid claim of the '318 patent.

Second Counterclaim

13. Alphapharm realleges the allegations contained in the preceding paragraphs 1-12 as if fully set forth herein.

14. The '318 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code.

PRAYER FOR RELIEF

WHEREFORE, Defendant Alphapharm respectfully requests that:

- a) The Complaint of Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. be dismissed with prejudice;
- b) The filing of Alphapharm's ANDA No. 77-603 be declared not to infringe any valid claim of the '318 patent;
- c) The manufacture, use, offer to sell, sale, and/or importation into the United States of Alphapharm's galantamine hydrobromide tablets that are the subject of Alphapharm's ANDA No. 77-603 be declared not to infringe any valid claim of the '318 patent;
- d) The '318 patent be declare invalid;
- e) Alphapharm be awarded its costs in this action;
- f) Alphapharm be awarded its attorneys' fees pursuant to 35 U.S.C. § 285; and
- g) Alphapharm be awarded such other and further relief as this Court may deem just and proper.

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Dated: August 11, 2005

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on August 11, 2005, I electronically filed the foregoing with the Clerk of Court using CM/ECF which will send notification of such filing to the following and which has also been served as noted:

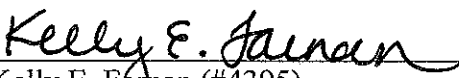
BY HAND

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I further certify that on August 11, 2005, the foregoing document was sent to the following non-registered participants in the manner indicated::

BY FEDERAL EXPRESS

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